510(k) Summary

K063679

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421

Contact Person:

Carol Marble, Regulatory Affairs Director
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JAN 12 2007

Prepared:

December 8, 2006

Device Name:

ACL TOP

Regulatory Information:

81GKP	Instrument, Coagulation, Automated	
864.5400	Coagulation Instrument	Class II

Predicate Device:

K033414 ACL TOP

Device Description:

The ACL TOP is a bench top, fully automated, random access analyzer designed specifically for *in vitro* diagnostic clinical use in the hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis. The system provides results for both direct hemostasis measurements and calculated parameters.

Reason for Submission:

The ACL TOP system software and test parameters are being modified to optimize the performance of the intrinsic and extrinsic factor assay applications on the instrument.

Major software/test parameter modifications to the factor assays include:

1. The calibration levels are now prepared by aspirating the calibrator directly from the calibrator vial (direct dilution instead of serial dilution).
2. The number of calibration points is being increased from 5 to either 7 or 8, dependent on the individual factor.
3. New mathematical tools are being implemented for generating the calibration curve, e.g. polynomial curve fitting capability as well as the capability for using segmented calibration curve (two different calibration curves for the lower and upper ends).
4. The robustness of the assays is increased by optimizing incubation time, transport air gap and probe rinse parameter modifications.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

The performance of the optimized factor assay applications on the ACL TOP (K033414) is substantially equivalent to the performance of the current legally marketed factor assay applications on the ACL TOP (K033414).

NOTE: There are no changes to the formulation of the factor assays, and no changes to the intended use/indications for use or labeled performance claims of either the ACL TOP or the factor assays with this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Co.
113 Hartwell Avenue
Lexington, MA 02421

Re: k063679
Trade/Device Name: ACL TOP
Regulation Number: 21 CFR § 864.5400
Regulation Name: Coagulation Instrument
Regulatory Class: II
Product Code: GKP
Dated: January 4, 2007
Received: January 5, 2007

JAN 12 2007

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K063679

Device Name: ACL TOP

Indications for Use:

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The system provides results for both direct hemostasis measurements and calculated parameters.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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